EXHIBIT 1

UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF LOUISIANA

IN RE: VIOXX **PRODUCTS LIABILITY LITIGATION**	MDL NO. 1657 SECTION L JUDGE FALLON MAG. JUDGE KNOWLES

THIS DOCUMENT RELATES TO: ***Jo Levitt v. Merck Sharp & Dohme Corp.*, 06-9757**

ORDER & REASONS

Before the Court are Defendant Merck's Motions to Exclude the Expert Opinions of David Madigan, M.D. (R. 65382), Thomas Rosamond, M.D. (R. 65384), Jay Schapira, M.D. (R. 65387), and David Egilman, M.D. (R. 65390). Plaintiff opposes each of the Motions. (R. 65407, 65408, 65410, and 65415). The Court heard oral argument from counsel at a hearing on Wednesday, August 17, 2016. After considering those arguments, the Court has reviewed the parties' submissions and applicable law, and now issues this Order & Reasons.

I. BACKGROUND

To put this matter in perspective, a brief review of this multidistrict litigation ("MDL") is appropriate. This litigation involves products liability claims pertaining to the prescription drug Vioxx, known generically as Rofecoxib. Merck, a New Jersey corporation, researched, designed, manufactured, marketed, and distributed Vioxx to relieve pain and inflammation resulting from osteoarthritis, rheumatoid arthritis, menstrual pain, and migraine headaches. On May 20, 1999, the Food and Drug Administration ("FDA") approved Vioxx for sale in the United States. Vioxx remained publicly available until September 30, 2004, when Merck withdrew it from the market after data from a clinical trial known as APPROVe indicated that the use of Vioxx increased the risk of cardiovascular thrombotic events such as myocardial infarction (that is, heart attack) and

ischemic stroke. Thereafter, thousands of individual suits and numerous class actions were filed against Merck in state and federal courts throughout the country alleging various products liability, tort, fraud, and warranty claims.

On September 29, 2006, Jo Levitt brought this action against Merck in the United States District Court for the Western District of Missouri. In her complaint, she alleges that she suffered two heart attacks in 2001 as a result of taking Vioxx and seeks compensatory and punitive damages, as well as interest, costs, attorneys' fees and any other available relief. On November 8, 2006, the matter was transferred to this Court for inclusion in the *Vioxx* MDL.

Following six "bellwether" trials in this proceeding—as well as trials in other proceedings in Alabama, California, Illinois, Florida, New Jersey, and Texas—the negotiating plaintiffs' counsel ("NPC") and Merck's counsel engaged in protracted settlement discussions over the course of a year, conducting hundreds of in-person and telephone meetings. On November 9, 2007, the parties announced a $4.85 billion master settlement agreement ("MSA") that intended to—and actually did—resolve most Vioxx-related claims through a resolution program. In its recitals, the MSA expressly states that its purpose was to "establish a pre-funded, structured private settlement program . . . to resolve . . . claims against Merck involving heart attacks, ischemic strokes and sudden cardiac deaths." This was an "opt-in" program, meaning an interested claimant had to take affirmative steps to enroll in it. Ms. Levitt chose not to enroll, and instead proceeded to litigate her claim. This Court retained jurisdiction for the discovery phase of this case.

On November 14, 2013, this Court ordered that Ms. Levitt designate expert witnesses and provide their reports pursuant to Federal Rule of Civil Procedure 26(a)(2) on or before December 13, 2013. (R. 64688). Ms. Levitt timely designated five expert witnesses.

Of those, Dr. David Madigan proffered opinions relating to statistical issues with Merck's internal studies regarding the potential risks of Vioxx. Ms. Levitt also disclosed Dr. Thomas Rosamond, her cardiologist, and reserved the right to call any and all treating physicians and other providers as fact or expert witnesses regarding the nature and extent of her injuries and resulting damages. Of her treating physicians, Merck only deposed Dr. Arnold Katz, her rheumatologist, who testified he would have prescribed Vioxx even if he were told that Vioxx increased the risks of heart attacks in a certain segment of the population. Notably, Plaintiff was *pro se* during the original discovery period and never deposed Dr. Katz during that time. Merck deposed Dr. Katz twice. Ms. Levitt also disclosed Dr. Jay Schapira, who addressed specific causation with regard to her two heart attacks, and designated Dr. David Egilman as her expert concerning non-heart attack related injuries.

II. PRESENT MOTIONS

Defendant Merck filed Motions to Exclude the Expert Opinions of Dr. David Madigan (R. 65382), Dr. Thomas Rosamond (R. 65384), Dr. Jay Schapira (R. 65387), and Dr. David Egilman. (R. 65390). Plaintiff opposes each motion.

A. *Daubert* Legal Standard

Rule 702 of the Federal Rules of Evidence governs the admissibility of expert testimony. Rule 702 is in effect a codification of the United States Supreme Court's opinion in *Daubert v. Merrell Dow Pharmaceuticals*, 509 U.S. 579 (1993). In *Daubert*, the Supreme Court held that trial courts should serve as gatekeepers for expert testimony and should not admit such testimony without first determining that the testimony is both "reliable" and "relevant." *Id.* at 589.

The trial court is the gatekeeper of scientific evidence. *Daubert*, 509 U.S. at 596. It has a special obligation to ensure that any and all expert testimony meets these standards. *Id.* Accordingly, it must make a preliminary assessment of whether the reasoning or methodology

underlying the testimony is scientifically valid and whether the reasoning or methodology can be properly applied to the facts in issue. *Id.* at 592–93. In making this assessment, the trial court need not take the expert's word for it. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 147 (1997). Instead, when expert testimony is speculative or lacks scientific validity, trial courts are encouraged to exclude it. *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 279 (5th Cir. 1998).

In satisfying its "gatekeeper" duty, the Court will look at the qualifications of the experts and the methodology used in reaching their opinions and will not attempt to determine the accuracy of the conclusion reached by the expert. The validity or correctness of the conclusions is a determination to be made by the fact finder after the *Daubert* analysis.

Scientific testimony is reliable only if "the reasoning or methodology underlying the testimony is scientifically valid," meaning that such testimony is based on recognized methodology and supported by appropriate validation based on what is known. *Daubert*, 509 U.S. at 592–93. In *Daubert*, the Supreme Court set forth a non-exclusive list of factors to consider in determining the scientific reliability of expert testimony. *Id.* at 593–95. These factors are: (1) whether the theory has been tested; (2) whether the theory has been subject to peer review and publication; (3) the known or potential rate of error; (4) whether standards and controls exist and have been maintained with respect to the technique; and (5) the general acceptance of the methodology in the scientific community. *Id.* Whether some or all of these factors apply in a particular case depends on the facts, the expert's particular expertise, and the subject of his testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 138 (1999).

In addition to the five factors laid out in *Daubert*, a trial court may consider additional factors to assess the scientific reliability of expert testimony. *Black v. Food Lion, Inc.*, 171 F.3d 308, 312 (5th Cir. 1999). These factors may include: (1) whether the expert's opinion is based on

incomplete or inaccurate dosage or duration data; (2) whether the expert has identified the specific mechanism by which the drug supposedly causes the alleged disease; (3) whether the expert has unjustifiably extrapolated from an accepted premise to an unfounded conclusion; (4) whether the expert has adequately accounted for alternative explanations; and (5) whether the expert proposes to testify about matters growing directly out of research he or she has conducted independent of the litigation. *See, e.g.*, *id.* at 313; *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278–79 (5th Cir. 1998); *Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1114 (5th Cir. 1991); *Newton v. Roche Labs., Inc.*, 243 F. Supp. 2d 672, 678 (W.D. Tex. 2002). Scientific testimony is relevant only if the expert's reasoning or methodology can be properly applied to the facts at issue, meaning there is an appropriate fit between the scientific testimony and the specific facts of the case. *Daubert*, 509 U.S. at 593. Scientific evidence is irrelevant, however, when there is too great an analytical gap between the data and the opinion proffered. *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997).

The party seeking to introduce the expert testimony bears the burden of demonstrating that the testimony is both relevant and reliable. *Moore*, 151 F.3d at 275–76. The requirement of reliability does not strictly bind an expert within the proffered field of expertise; an expert may also testify concerning related applications of his or her background. *Slatten, LLC v. Royal Caribbean Cruises Ltd.*, No. 13-673, 2014 WL 5393341, at *2 (E.D. La. Oct. 23, 2014) (citing *Wheeler v. John Deere Co.*, 935 F. 2d 1090, 1100 (10th Cir. 1991). The focus is not on the result or conclusion, but on the methodology. *Moore*, 151 F.3d at 275–76. The proponent need not prove that the expert's testimony is correct, but must prove by a preponderance of the evidence that the expert's methodology was proper. *Id.* Here, Merck has filed motions to exclude four different experts in this case. The Court will address each of the motions in turn.

B. Motion to Exclude Opinions of Mr. David Madigan (R. 65382)

1. Parties' Arguments

Merck argues that the Court should exclude the expert opinions of Dr. Madigan concerning (1) subjects outside his expertise, including the adequacy of Merck's disclosures to healthcare professionals; (2) factual narratives designed to describe Merck's "state of mind"; and (3) an undisclosed statistical analysis that a different Plaintiff's expert, Dr. Egilman, has testified that he intends to rely on. R. 65382 at 1. Despite Dr. Madigan's expertise in statistics, Merck contends that this qualification is insufficient to support much of Dr. Madigan's testimony. R. 65382 at 2.

In particular, Merck challenges Dr. Madigan's opinions regarding Merck's disclosures of Vioxx risk information. Merck argues that only an expert qualified in the field of medicine can speak to the analysis of the cardiovascular risk data in the studies at issue. R. 65382 at 7. Merck also challenges Dr. Madigan's qualifications insofar as he opines on Merck's state of mind. Merck claims that Dr. Madigan should be prohibited from testifying regarding Merck's assessment of the value of trial data. R. 65382 at 12.

Lastly, Merck asserts that Madigan should be prohibited from opining regarding a statistical analysis concerning a cardiovascular event, unstable angina, which he conducted following his deposition. R. 65382 at 13. Madigan's expert witness report did not reference this study and his deposition testimony did not indicate that he was aware of any studies with findings similar to the study at-issue. R. 65382 at 13–15. Merck also argues that this study should be excluded because it will be relied upon by a separate Levitt expert, Dr. Egilman, and will be misleading if not adequately explained. R. 65382 at 14.

Levitt opposes the motion and argues Dr. Madigan does not seek to testify as to issues requiring medical expertise. R. 65407 at 7. Instead, Levitt argues Dr. Madigan will only proffer opinions based on his extensive experience in clinical trials regarding biostatistics, epidemiology,

and pharmacoepidemoiology. R. 65407 at 8. Levitt concedes that experts are generally disqualified from providing narrative testimony. However, Levitt argues that Dr. Madigan is permitted to articulate the factual underpinning on which his opinions are based. R. 65407 at 13–14.

Finally, Levitt contends that Dr. Madigan should be allowed to present his recently completed statistical analysis of Vioxx data. R. 65407 at 15. Dr. Madigan's report was completed on December 8, 2013 and his deposition took place March 7, 2016. R. 65407 at 15. Dr. Egilman was deposed on April 12, 2016. R. 65407 at 15. Levitt argues that Merck has waived its objection to the report, because Merck has had several months to re-depose Dr. Madigan following the first mention of the report at Dr. Egilman's deposition. R. 65407 at 15. Levitt therefore argues Merck cannot show sufficient prejudice to exclude a "relevant and reliable" statistical analysis. R. 65407 at 15–16.

1. Analysis

Merck's criticism of Dr. Madigan does not warrant exclusion. Dr. Madigan is currently a professor and chair of statistics at Columbia University. He has a degree in mathematics and a Ph.D. in statistics. However, Dr. Madigan is not a medical doctor. He has no clinical experience, has not held a position in a medical school, and has no experience in weighing the risks and benefits of medical treatment, including pharmaceuticals. He is not an epidemiologist and does not claim to have experience designing or conducting clinical drug trials. He is not an expert in pharmacology, cardiology, rheumatology, gastroentology, neurology, vascular biology, or any other medicine related to Vioxx. While Dr. Madigan recently began serving on an FDA advisory committee, he has never worked for the FDA, nor is he an expert on FDA labeling requirements or regulatory compliance.

Based on these qualifications, it is not clear what assistance Dr. Madigan can offer the fact finder in this case. Dr. Madigan's expert experience is exclusively in the fields of mathematics and

statistics. Reliance upon specialized knowledge is an acceptable ground for the admission of expert testimony. *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 152 (1999); *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 247 (5th Cir. 2002). However, an expert cannot "go beyond the scope of his expertise in giving his opinion." *Goodman v. Harris County*, 571 F.3d 388, 399 (5th Cir. 2009).

However, Dr. Madigan does have extensive experience with mathematics and statistics. Therefore, if he is tendered as an expert his testimony and opinions should be related to these fields. He may offer opinions regarding the field of statistics, how they are compiled, and their general use. Inasmuch as Dr. Madigan's recently completed report aids in this testimony, he should be permitted to rely on it, as the report is not so prejudicial as to warrant exclusion.

Nonetheless, Dr. Madigan should not be allowed to opine on Merck's actions or inactions in disclosing or not disclosing various results. Similarly, Dr. Madigan should not offer opinions regarding Merck's interpretations of the test results or their significance. Such testimony would be outside his field of expertise, and therefore inadmissible under the *Daubert* standard.

C. Motion to Exclude Opinions of Dr. Thomas Rosamund (R. 65384)

1. Parties' Arguments

Dr. Rosamond treated Levitt on March 9, 2000 at St. Luke's Hospital South, where she presented with acute unstable angina. R. 65384 at 2. Merck argues that the Court should exclude Dr. Rosamond's case-specific statement (or *Lone Pine* letter[1]) of his medical treatment of Levitt because it relies on retrospective knowledge of the Vioxx litigation, as Dr. Rosamund formed his opinion at least seven years after he treated Levitt. R. 65384 at 6–9. Merck also claims that Dr. Rosamond's two-page case-specific statement fails to qualify as a Rule 26(a)(2)(B) expert report

[1] In Pretrial Order No. 28, this Court required plaintiffs in the Vioxx MDL to provide a case-specific statement. R. 12962. These statements are commonly referred to as *Lone Pine* letters.

and thus Dr. Rosamund is procedurally barred from serving as an expert witness in this case. R. 65384 at 3–6.

Levitt disagrees, and asserts that the Court has already ruled on the admissibility of Dr. Rosamund's testimony.[2] Further, Levitt argues that Dr. Rosamund intends to testify as Levitt's treating physician, and not as an expert witness retained for this litigation. R. 65408 at 5. Levitt contends that experts retained by a party must provide an expert report pursuant to Rule 26, but treating physicians do not have to meet this same requirement. R. 65408 at 5. Finally, Levitt argues that Merck cannot claim a lack of notice, because Merck received a Rule 26(a)(2)(C) report that stated Dr. Rosamond's intention to opine as to Levitt's medical condition, medical care, and/or medical treatment. R. 65408 at 10–11.

2. Analysis

First, as Ms. Levitt's treating physician, Dr. Rosamund is allowed to testify without providing a written report. While witnesses who are "retained or specially employed to provide expert testimony" must submit a written expert report, this requirement does not apply to treating physicians.[3] Fed. R. Civ. Proc. 26. Furthermore, expert testimony is admissible where it is "based on the expert's specialized knowledge, training, experience, and first-hand observation while supported by solid evidence in the scientific community." *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 247 (5th Cir. 2002).

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[2] Levitt directs the Court to its April 21, 2015, Order & Reasons. Levitt contends that in this Court's April 21, 2015 Order & Reasons, the Court held that Dr. Rosamund's testimony should not be excluded on the grounds that he formed his opinions regarding specific causation after he had ceased to be Ms. Levitt's treating physician. R. 65408 at 4–5.

[3] "The requirement of a written report in paragraph (2)(B), however, applies only to those experts who are retained or specially employed to provide such testimony in the case or whose duties as an employee of a party regularly involve the giving of such testimony. A treating physician, for example, can be deposed or called to testify at trial without any requirement for a written report." Fed. R. Civ. P. 26 advisory committee's note to 1993 amendment.

In addition, Dr. Rosamund is a trained physician, who treated Ms. Levitt prior to this litigation. As such, he shall be allowed to testify to the observations and conclusions he made during her treatment without submitting a written report. However, Dr. Rosamund's testimony is restricted to the opinions he formed during the period of time he administered treatment to Ms. Levitt. All of his opinions before the Court must be based on his experience as the treating physician, as that is the basis of his expertise.

D. Motion to Exclude Opinions of Dr. Jay Schapira (R. 65387)

1. Parties' Arguments

Merck argues that the Court should exclude Dr. Schapira's opinions concerning (1) causation; (2) whether Levitt experienced a myocardial infarction, and (3) subjects outside his expertise, including psychology, disability, and business analysis.

First, Merck contends that Dr. Schapira has failed to meaningfully review the literature regarding Vioxx and cardiovascular events and therefore cannot offer opinions regarding causation. Turning to Dr. Schapira's opinion that Levitt experienced a myocardial infarction, Merck claims that Dr. Schapira's views are unreliable as he has changed his position regarding whether, and on what dates, a myocardial infarction occurred multiple times. R. 65387 at 7. Merck additionally avers that the Court should discount Dr. Schapira's testimony because he is the only expert to conclude that a myocardial infarction occurred, and that he conceded that Levitt's most recent cardiovascular imaging revealed no sign of prior myocardial infarction. R. 65387 at 8–9. Finally, Merck asserts that Dr. Schapira's testimony should be restricted to his opinions on cardiology, and that his opinions regarding the psychological or financial impact of the cardiovascular events had on Levitt should be excluded. R. 65387 at 10.

Levitt disagrees and asserts that Dr. Schapira's opinions are sufficiently supported to be offered as reliable causation testimony. R. 65410 at 5. In support of her argument, Levitt explains

that Dr. Schapira's expert report refers to two Vioxx-related publications, one of which considered eighteen randomized control trials and eleven observational studies. R. 65410 at 6. Additionally, Levitt asserts that Dr. Schapira relied upon numerous other articles and publications in forming his conclusions. R. 65410 at 6–7.

Levitt also avers that Dr. Schapira's opinion that Levitt suffered a myocardial infarction has remained consisted throughout this litigation. R. 65410 at 10–11. While Levitt concedes that Dr. Schapira amended his report to state that Levitt suffered from acute coronary syndrome, she argues that the original diagnosis of acute myocardial infarction and unstable angina falls within the bounds of the inclusive term "acute coronary syndrome." R. 65410 at 11–12.

Lastly, Levitt contends that Dr. Schapira is qualified to opine as to depression, cognitive issues, and a "global disability" associated with Levitt's cardiovascular injuries. Dr. Schapira has been a practicing physician for thirty-eight years, and he routinely diagnosed patients with depression and other cognitive issues over the course of his cardiovascular practice. R. 65410 at 15–16. As such, Levitt contends that Dr. Schapira's opinions as to Levitt's depression and cognitive issues are within his field of expertise. R. 65410 at 16–17.

2. Analysis

After reviewing Dr. Schapira's qualifications, report, his deposition testimony, and the materials upon which he relied, the Court finds his report and opinions admissible because they are based on his specialized knowledge and experience.

Merck's objections primarily concern Dr. Schapira's qualifications. Dr. Schapira is a board certified clinical cardiologist and internist. He reviewed Levitt's medical history as well as multiple reports from her doctors. He also looked at the medical literature. Expert testimony based on specialized knowledge, training and experience is admissible when supported by scientific evidence. *Pipitone v. Biomatrix, Inc.*, 288 F.3d 239, 247 (5th Cir. 2002). The Court finds Dr.

Schapira has specialized knowledge, training, and experience in diagnosing cardiovascular injuries. As such, Dr. Schapira is qualified to testify as to the Plaintiff's cardiovascular injuries and their cause.

The Defendant's objections go to the credibility and weight of the doctor's testimony, rather than its admissibility. Additionally, Merck's arguments focus on the validity of his conclusions rather than Dr. Schapira's methodology. These concerns are best addressed during cross examination at trial, and are insufficient grounds to exclude his testimony under *Daubert*. *See Daubert v. Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579, 596 (1993). "Vigorous cross-examination, presentation of contrary evidence, and careful instruction on the burden of proof are the traditional and appropriate means of attacking shaky but admissible evidence." Thus, Dr. Schapira's expert testimony is admissible under *Daubert*.

E. Motion to Exclude Opinions of Dr. David Egilman (R. 65390)

1. Parties' Arguments

Levitt presents Dr. Egilman as an expert in cardiology, toxicology, molecular biology, neurology, psychiatry, prescription drug marketing, regulatory compliance, ethics, corporate state of mind, and the law. Merck argues that Dr. Egilman is merely a retired general-practice physician who lacks sufficient medical expertise to testify regarding any alleged risk of Alzheimer's disease, dementia, cognitive dysfunction, restenosis, or accelerated atherosclerosis posed by Vioxx. R. 65390 at 6–7, 9–10. Merck contends that Dr. Egilman's background as a family practice doctor does not provide the education or experience necessary to allow him to opine on these points. R. 65390 at 6–8. Similarly, Merck avers that Dr. Egilman cannot testify as to Levitt's psychiatric health, because Dr. Egilman is not qualified in the field of psychiatry. R. 65390 at 8–9. Furthermore, Merck argues that Dr. Egilman is unqualified to opine regarding Merck's state of

mind, Merck's allegedly unethical marketing strategies, Merck's alleged non-compliance with regulatory opinions, and Merck's allegedly illegal activities. R. 65390 at 14–22.

Merck also disputes Dr. Egilman's findings that Vioxx is associated with unstable angina. Merck contends that district courts should exclude studies that look at composite risks for a broad set of adverse outcomes such as unstable angina, cardiac arrest, and sudden death, rather than a specific connection between the particular exposure and the actual affliction experienced by the plaintiff, unstable angina. R. 65390 at 11 (citing *Burleson v. Tex. Dep't of Crim. Justice*, 393 F.3d 577, 585 (5th Cir. 2004). In essence, Merck argues that Dr. Egilman's study suggests that Vioxx is causally linked to a set of heart-related incidents that includes unstable angina, but does not in and of itself prove that Vioxx causes unstable Angina. Merck contends that other cardiovascular endpoints such as cardiac arrest are driving the association in the study. R. 65390 at 12–13.

Levitt counters that Dr. Egilman has extensive training and experience that qualifies him to opine on these points. Specifically, Dr. Egilman has a Masters of Public Health from Harvard University, has published articles on conflicts of interest in the context of public health, and testified in the first Vioxx bellwether trial in Texas. R. 65415 at 3–6. Additionally, Dr. Egilman has testified in numerous courts throughout the country on issues similar to the opinions presented in this case. R. 65415 at 10. Levitt contends that Dr. Egilman is qualified to testify as to the emotional components of a disease because he has "researched and studied the correlation between psychological effects such as depression and cardiac events and has treated his own patients for psychological issues." R. 65415 at 11–12.

Levitt denies that Dr. Egilman intends to opine on Merck's state of mind or offer ethics opinions. However, Levitt maintains that Dr. Egilman is qualified to discuss Merck's marketing and warnings based on his specialized training and research. Dr. Egilman took a course on

warnings as risk communication, has published several papers on warnings, teaches on the topic, and has co-authorized two textbook chapters on warnings. R. 65415 at 14–15. For these reasons, Levitt argues that Dr. Egilman is qualified to compare Merck's marketing messages with what the underlying scientific research showed. R. 65415 at 17–18. Similarly, Levitt contends that Dr. Egilman is qualified to testify regarding Merck's compliance with FDA regulations, as Dr. Egilman has been accepted as an expert on the issue of warnings and FDA policy and issues that relate to FDA warning policy. R. 65415 at 19–20.

Lastly, Levitt addresses Merck's contention that Dr. Egilman may not rely on Dr. Madigan's causation analysis. Levitt argues that Dr. Egilman may cite a study which is in agreement with his own conclusions. R. 65415 at 21–24. Levitt further avers that Dr. Madigan's study should not be limited to data on unstable angina alone, because Merck holds all of the charts containing information that is exclusive to unstable angina. R. 65415 at 25. Levitt also points out that numerous opinions have found that acute coronary syndrome is causally linked to Vioxx. R. 65415 at 26. Because acute coronary syndrome includes unstable angina, Levitt avers that Dr. Egilman should be allowed to use an analysis linking acute coronary syndrome to Vioxx as evidence that Vioxx caused Ms. Levitt's injuries. R. 65415 at 26.

Merck then reiterates that Dr. Egilman should not be permitted to testify regarding Dr. Madigan's study finding that Vioxx is linked to acute coronary syndrome, and therefore to unstable angina. R. 65431 at 6. According to Merck, Fifth Circuit law requires statistical analyses to isolate the particular injury suffered by a plaintiff, and not merely a umbrella category of diseases containing that specific disease. R. 65431 at 6–7. Merck avers that Levitt's response to this point—that Merck's studies do not report unstable angina separately—is false. R. 65431 at 6–7. According to Merck, Levitt received an expert report from Merck that specifically lists the incidence of

unstable angina for each Vioxx trial. R. 65431 at 6–7. Merck also argues that Dr. Egilman should not be allowed to refer to Dr. Madigan's study on the grounds that Dr. Egilman cannot testify as to Dr. Madigan's methodology.

After oral argument, the parties filed stipulations with the Court addressing the testimony of Dr. Egilman. R. Doc. 65453. Per that agreement, Dr. Egilman will not offer testimony regarding the following:

- Specific causation opinions that Vioxx is causally associated with or caused Jo Levitt to suffer from Alzheimer's disease, dementia, or cognitive impairment.
- General or specific causation opinions that Vioxx is causally associated with atherosclerosis, atherogenesis, or restenosis.
- Ethics opinions, including opinions that Merck violated any duties or standards, or that Merck's conduct was wrong or immoral.
- Testimony regarding Merck's state of mind.

However, the parties still disagree whether Dr. Egilman should be allowed to testify regarding various specialized fields of medicine, such as epidemiology, neurology, and psychiatry, as well as general causation opinions associating Vioxx with Alzheimer's and cognitive dysfunction, and opinions regarding Ms. Levitt's psychiatriac health. In addition, the parties dispute whether Dr. Egilman should be permitted to opine about an acute coronary syndrome meta-analysis performed by Dr. Madigan. Finally, the parties disagree regarding whether Dr. Egilman's opinions that Vioxx is causally associated with unstable angina is based on reliable methodology. Thus, the Court finds it necessary to address these issues.

2. Analysis

Dr. Egilman is a board certified doctor and internist. He has completed advanced study in the areas of epidemiology, occupational medicine, warnings, and risk communication, among other topics. He has written extensively on the topic of medical epistemology. As such, Dr.

Egilman is qualified to offer opinions based on his expertise, including epidemiology. The fact that he frequently testifies in claims against pharmaceutical companies is not grounds for disqualification, but is a topic best explored during cross examination.

While Merck contents Dr. Egilman is unqualified to opine as to Levitt's emotional health, Dr. Egilman's experience as a family doctor provides him an adequate basis for rudimentary observations regarding Levitt's psychiatric and emotional well-being. Similarly, Dr. Egilman is qualified to offer basic opinions in the field of neurology to the extent such opinions are limited to what may be observed by a general family doctor. However, any diagnostic opinions regarding Levitt's emotional or psychiatric state, or extensive conclusions in the specialized field of neurology are outside his area of expertise, and therefore inadmissible. *See Goodman v. Harris County*, 571 F.3d 388, 399 (5th Cir. 2009) (holding an expert may not "go beyond the scope of his expertise in giving his opinion.").

The parties also disagree as to whether Dr. Egilman should be permitted to offer any opinions he formed after reviewing Dr. Madigan's report. Under Federal Rule of Evidence 703, an expert may base opinions on facts or data he has been made aware of during the case. Fed. R. Evid. 703. This includes other expert reports in the case. *See Christophersen v. Allied-Signal Corp.*, 939 F.2d 1106, 1111 (5th Cir. 1991) (abrogated on other grounds) ("The reports and statements of others . . . while not as valuable as testimony based on the expert's own observations, can provide a reliable basis for the expert's opinion, at least when reliance on such sources is the custom of the discipline."). Thus, Dr. Egilman's conclusions based on Dr. Madigan's report are admissible.

Merck correctly points out that under Fifth Circuit precedent, Dr. Egilman's testimony would be restricted to the relationship between Vioxx and the specific injury at issue here—

unstable angina. *See Allen v. Pennsylvania Eng'g Corp.*, 102 F.3d 194, 197 (5th Cir. 1996). Under this rule, Dr. Egilman cannot utilize a study linking Vioxx to general cardiac events—which may include unstable angina—to prove that Vioxx is directly linked to unstable angina.

For example, in *Allen v. Pennsylvania Eng'g Corp*, a plaintiff was diagnosed with brain cancer after working at a hospital where he was exposed to ethylene oxide ("EtO") for more than twenty years. *Allen*, 102 F.3d. at 195. After the plaintiff's death, his widow brought a products liability action against the manufacturer of EtO, claiming the chemical was the cause of his brain cancer. *Id.* The trial court held the causation testimony of the plaintiff's expert was inadmissible under the *Daubert* standard. *Id.* at 198. The Fifth Circuit affirmed, finding the causation testimony unreliable. *Id.* In particular, the court noted the expert relied on studies demonstrating a link between EtO exposure and cancer—but not the particular type of brain cancer at issue in the case. *Id.* Without a statistical study linking EtO exposure to the particular injury the plaintiff suffered, the expert could not testify regarding causation. *Id.* Thus, under Fifth Circuit law, Dr. Egilman's testimony that Vioxx is causally associated with unstable angina—as opposed to general cardiac events—likely has too great of an analytical gap between the data and his opinions to meet the *Daubert* standard.

However, this case will not be tried in the Fifth Circuit, and this Court is unaware of any Eighth Circuit or Missouri cases directly addressing this issue.[4] In addition, the United States Court of Appeals for the First Circuit has taken a different approach, and has allowed experts to testify that a particular exposure was linked to a specific injury when statistical studies demonstrated the

[4] In *Mascarenas v. Miles, Inc.*, the Western District of Missouri relied on the Fifth Circuit's holding in *Allen v. Penn. Eng'g Corp*, however the court applied Texas law in that case. There, the court excluded expert testimony in part because the expert was unable to provide a direct link between the exposure and the particular cancer at issue. *See Mascarenas v. Miles*, Inc., 986 F. Supp. 582, 593 (W.D. Mo. 1997) (applying *Allen v. Penn. Eng'g Corp,* 102 F.3d 194 (5th Cir. 1996).

exposure caused a class of various injuries, including the specific disease at issue. *See Milward v. Acuity Specialty Prod. Grp., Inc.*,639 F.3d 11, 20 (1st Cir. 2011).[5] In light of these differing approaches, and the fact that no court has addressed this issue under Missouri law, the trial court should determine whether Dr. Egilman's testimony that Vioxx is causally associated with unstable angina meets the *Daubert* requirements under Missouri law.

III. CONCLUSION

For the aforementioned reasons, **IT IS ORDERED** that Defendant's Motion to Exclude the Testimony of Dr. David Madigan, R. 65382, is **GRANTED IN PART** and **DENIED IN PART.**

IT IS FURTHER ORDERED that Defendant's Motion to Exclude the Testimony of Dr. Thomas Rosamond, R. 65384, is **DENIED.**

IT IS FURTHER ORDERED that Defendant's Motion to Exclude the Testimony of Dr. Jay Schapira, R. 65387, is **DENIED.**

IT IS FURTHER ORDERED that Defendant's Motion to Exclude the Testimony of Dr. David Egilman, R. 65390, is **GRANTED IN PART** and **DENIED IN PART.**

New Orleans, Louisiana, this 16th day of September, 2016.

UNITED STATES DISTRICT JUDGE

[5] In *Milward v. Acuity Specialty Prod. Grp., Inc.*, the United States Court of Appeals for the First Circuit allowed an expert to testify that because benzene causes acute myeloid leukemia ("AML"), it was also capable of causing a specific subtype of AML. In particular, the expert noted "all subtypes of AML likely have a common etiology," and this particular subtype has been reported in many other workers who were also exposed to benzene. 639 F.3d 11, 20 (1st Cir. 2011).